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Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

# APPEAL BRIEF

## (1) REAL PARTY IN INTEREST.

The real party in interest is DIESSE DIAGNOSTICA SENESE S.P.A.

## (2) RELATED APPEALS AND INTERFERENCES.

There are believed to be no related appeals and interferences.

## (3) STATUS OF CLAIMS.

Claims 1-11, 13-34 and 41-52 are on appeal.

Claims 12 and 35 - 40 have been canceled.

Claims 1-11, 13-17, 21-28, 41 - 44 and 46-52 have been rejected under 35 U.S.C.

102(b) as being anticipated by Skotnikov et al. (US 5,526,705).

Claims 18-20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Kaarkainen et al. (US 6,520,313).

Claims 29, 30 and 32-34 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Coulter et al. (US 4,609,017).

Claim 31 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Coulter et al. and in further view of Roginski (US 4,927,545).

(4) STATUS OF AMENDMENTS.

An After Final Amendment has not been filed in response to the final rejection of January 22, 2010.

(5) SUMMARY OF THE CLAIMED SUBJECT MATTER

CLAIM 1:

Claim 1 is directed to an erythrocyte sedimentation rate measuring device for blood samples (Figure 1). Conventional techniques require that blood be drawn from a test tube and aspirating part of the blood sample into a capillary tube wherein the erythrocyte sedimentation rate is measured inside the capillary tube. This disadvantageously increases solid and liquid waste since the blood sample in conventional techniques requires that the capillary tube be subsequently washed or replaced between one test and the next test. This significantly increases production costs due to having to dispose of the liquid and solid waste produced in

conventional techniques. Further, conventional techniques provide an inherent risk of contamination between the samples analyzed in series. Appellant's device overcomes the problems of conventional techniques of determining an erytrhocyte sedimentation rate by providing a device that does not require the samples to be removed from a test tube in order to determine the erythrocyte sedimentation rate. This significantly reduces production costs since the samples do not have to be removed in order to determine the erythrocyte sedimentation rate.

The device 2 (page 20, lines 1-3; Figure 1) comprises holders 3 for test tubes P containing samples of biological fluids (page 3, lines 12-18; page 20, lines 3-5; Figures 1 - 4). Agitator devices 25 are provided for agitating the test tubes P (page 23, lines 2-4; Figures 8-11). At least a first detector 17 and a second detector 19 are provided for detecting the levels inside the test tubes P (page 20, line 16 through page 21, line 4; Figure 1). A control unit 47, 275 is provided (page 5, lines 17-20; page 26, lines 14-16; page 36, lines 4-5; Figure 1). The holders 3 are formed in a continuous flexible member 1 that defines a closed path (page 14, lines 6-9; page 27, lines 6-9; Figure 1). The agitator devices 25, the first detector 17 and the second detector 19 are arranged in sequence along the path (Figure 1). The first detector 17 is located at a spaced location from the second detector 19 via a sedimentation area (page 25, lines 9-10; page 34, lines 3-5; Figure 1; Figure 23). The control unit 47, 275 determines the erythrocyte sedimentation rate based on levels inside the test tubes P detected by the first detector 17 and the second detector 19 (page 6, lines 4-10; page 40, lines 12-16).

CLAIM 2:

The agitator devices 25 of claim 1 may be arranged such that the agitator devices 25 oscillate the holders 3 such that the fluid in the holders 3 is stirred (page 12, lines 15-18).

CLAIM 3:

At least one agitating area may be arranged along the closed path of claim 1, wherein the agitator devices 25 are provided in the agitating area (page 11, lines 8-10). The sedimentation area may be located along the closed path (page 11, lines 8-10; Figure 1). At least one reading area may be arranged along the closed path wherein one of the first detector 17 and the second detector 19 is installed (page 11, lines 8-10; page 34, lines 17-19; Figure 1; Figure 23).

CLAIM 4:

The flexible member 1 of claim 1 may define a path lying on a substantially horizontal plane (page 12, lines 1-3; Figure 1).

CLAIM 5:

The holders 3 of claim 1 may comprise elements (Figures 2-4; Figure 7) interconnected to form a flexible chain member 1 (page 12, lines 4-8; page 20, lines 1-3; page 21, line 16 through page 22, line 1; Figures 1-7).

CLAIM 6:

Each of the elements (Figures 2-4; Figure 7) of claim 5 may comprise a single seat 3C for a respective test tube P (page 12, lines 9-11; page 22, lines 2-3; Figure 5; Figure 6).

CLAIM 7:

The elements (Figures 2-4; Figure 7) of claim 5 that form the flexible member 1 may connected together by means of couplings 3A, 3B (page 12, lines 4-8; Figure 1; Figure 7). The flexible member 1 may move in a traveling direction F1 (page 24, lines 11-15; Figure 1; Figure 21). Each of the holders 3 may be mounted for movement such that each of the holders 3 is rotatable with respect to an adjacent holder about a horizontal axis (page 24, lines 9-15; Figure 10; Figure 11). The horizontal axis may be parallel to the traveling direction (page 13, lines 5-11; Figure 1). One or more of the holders 3 may rotate about the horizontal axis via at least one of the agitator devices 25 so that fluid in one or more of the holders 3 is stirred via at least one of the agitator devices 25 (page 24, line 2 through page 25, line 5).

CLAIM 8:

The couplings 3A, 3B of claim 7 may be composed of spherical joints (page 21, line 16 through page 22, line 1; Figures 2-4; Figure 6; Figure 7).

CLAIM 9:

The agitator devices 25 of claim 4 may oscillate the elements (Figures 2-4; Figure 7)

forming the flexible chain member such that at least one of the holders 3 rotates about a horizontal axis defined by the continuous flexible member 1 (page 24, lines 2-15; Figures 8-11).

CLAIM 10:

The agitator devices 25 of claim 9 may comprise guides 39 (page 23, lines 12-16; Figure 8; Figure 11). The elements (Figures 2-4; Figure 7) may engage the guides 39 such that at least one of the holders 3 rotates about the horizontal axis via the guides 39 (page 24, lines 2-15).

CLAIM 11:

The elements (Figures 2-4; Figure 7) of claim 10 may have sliding shoes 3F that engage in the guides 39 (page 22, lines 6-8; Figure 3; Figure 5; Figure 11).

CLAIM 13:

The agitator devices 25 of claim 9 may comprise mobile guides 39 (page 23, lines 12-16; Figure 8; Figure 11). The mobile guides 39 extend along a portion of the path covered by the flexible member 1 (page 13, lines 12-14; Figure 8; Figure 10; Figure 11). The elements (Figures 2-4; Figure 7) forming the flexible member 1 are engaged with one another (page 21, lines 16-18; Figure 7; Figure 9; Figure 10). The guides 39 are mounted for movement such that the guides 39 rotate at least one holder about the horizontal axis X-X (page 24, lines 2-15;

Figures 8-11). The fluid in the at least one holder is mixed via rotation of the at least one holder (page 24, line 2 through page 25, line 5).

CLAIM 14:

The agitator devices 25 of claim 9 may comprise a rotor 27A, 27B coaxial to a portion of the path of the flexible member 1 (page 23, lines 5-9; Figure 9; Figure 10) and the rotor 27A, 27B may be provided with engaging elements 39 for engaging the holders 3 that come to be along the portion along the path of the flexible member 1 (page 24, lines 2-5; Figures 9-11). The rotor 27A, 27B may be mounted for movement such that the rotor rotates 27A, 27b or oscillates about an axis X-X thereof (page 23, lines 5-9; Figures 8-11).

CLAIM 15:

The engaging elements 39 of claim 14 may be in the form of guides 39 within which the holders 3 forming the continuous flexible member 1 are slidingly engaged (page 23, lines 12-18; Figure 9; Figure 10).

CLAIM 16:

The first detector of claim 1 may be arranged along the closed path, downstream from the agitator devices 25 (page 11, lines 17-20; Figure 1), and the second detector 19 may be arranged further along the path, downstream from a portion of path defining the sedimentation area (page 11, lines 17-20; page 25, lines 9-10; Figure 1).

CLAIM 17:

The device of claim 16 may further comprise a third detector 21 arranged along the path, downstream from a further portion of path defining a second sedimentation area (page 21, lines 2-7; Figure 1).

CLAIM 18:

The continuous flexible member 1 of claim 5 may comprise a transponder associated with each test-tube holder (page 14, lines 12-14; page 22, lines 3-6; Figure 2).

CLAIM 19:

Each of the elements (Figures 2-4; Figure 7) of claim 5 may be associated with a respective transponder (page 22, lines 3-5; Figure 2).

CLAIM 20:

Along the path of claim 18 there may be one or more stations for scanning the transponders (page 14, lines 18-20; page 15, line 18 through page 16, line 2).

CLAIM 21:

Along the closed path of claim 1 there may be at least one extractor 83 for removing the test tubes P from the holders 3 (page 15, lines 4-5; page 21, lines 8-9; page 30, lines 4-6; Figure 15; Figure 16).

CLAIM 22:

Along the closed path of claim 21 there may be two extractors for removing the test tubes P from the holders 3 and distributing them in respective containers 15 (page 15, lines 5-7; page 21, lines 8-15; Figure 1).

CLAIM 23:

The device of claim 1 may further comprise automatic manipulators for automatically inserting the test tubes P in the holders 3 (page 15, lines 11-13).

CLAIM 24:

The manipulators of claim 23 may move single test tubes P from a rack of test tubes and insert the test tubes P in the holders 3 (page 15, lines 13-15).

CLAIM 25:

The device of claim 1 may further comprise a setup unit 51 for preparing the test tubes P for insertion in the holders 3 (page 15, lines 15-18; page 19, lines 13-15; page 27, lines 6-7; page 27, lines 17-18; Figure 12).

CLAIM 26:

The setup unit 51 of claim 25 may be situated above the continuous flexible member 1 (page 27, lines 6-7).

CLAIM 27:

The setup unit 51 of claim 25 may comprise a reading station for automatically reading labels attached to the test tubes P, to ascertain in each case whether the test tubes must undergo a measurement of the sedimentation rate of the sample contained therein (page 15, line 18 through 2.

CLAIM 28:

The manipulators of claim 24 may be controlled and operated by a central unit 47 as a function of information provided for each test tube P by reading stations, to transfer the test tubes P in which the sedimentation rate must be measured from the rack to a corresponding holder (page 15, lines 11-13; page 26, lines 14-18).

CLAIM 29:

The setup unit 51 of claim 25 may comprise at least one first conveyor 53 for moving a plurality of racks containing test tubes P with samples of biological fluid to analyze (page 27, line 18 through page 28, line 1; Figure 12).

CLAIM 30:

The setup unit 51 of claim 29 may comprise a first transfer unit 61 for removing single racks R from the first conveyor 53 and transferring the single racks R to the reading station (page 28, lines 4-10; Figure 12).

CLAIM 31:

The manipulators of claim 24 may include a lower push bar 85 (page 30, lines 4-6; Figure 15). The lower push bar 85 may engage the test tubes P contained in the racks R such that the test tubes P slide partially out of the racks R (page 30, lines 9-13). The manipulators may comprise a mobile clamp 93 for removing the test tubes P from the respective racks R and inserting the test tubes P in corresponding holders 3 in the continuous flexible member 1 (page 30, lines 9-13; page 31, lines 3-5; Figure 12).

CLAIM 32:

The setup unit 51 of claim 29 may include a second conveyor 67 for moving a plurality of racks R and a second transfer device 69 for transferring the racks R from the second conveyor 67 to the first conveyor 53 (page 29, lines 2-6; Figure 12).

CLAIM 33:

The first transfer device 61 of claim 32 may transfer the racks R from the first conveyor 53 to the reading station and from the reading station to the second conveyor 67 (page 28, lines 4-9; page 28, line 15 through page 29, line 1).

CLAIM 34:

The device of claim 29 may further comprise means for identifying the status of each rack R associated with one or more of the first and second conveyors 53, 67 of the setup unit

51 (35 U.S.C. 112, sixth paragraph, page 29, lines 6-13).

CLAIM 41:

Along the closed path of claim 2 may be arranged the sedimentation area, at least one agitating area, wherein the agitator devices 25 are provided, and at least one reading area wherein one of the first detector 17 and the second detector 19 is installed (page 11, lines 8-10; Figure 1).

CLAIM 42:

The flexible member 1 of claim 2 may define a path lying on a substantially horizontal plane (page 12, lines 1-3).

CLAIM 43:

The flexible member 1 of claim 3 may define a path lying on a substantially horizontal plane (page 12, lines 1-3).

CLAIM 44:

The holders 3 may comprise elements (Figures 2-4; Figure 7) interconnected to form a flexible chain member 1 (page 12, lines 4-8; Figure 1; Figures 2-4; Figure 7).

CLAIM 45:

Along the path of claim 41, two readings may be taken on biological samples in each test tube P (page 21, lines 5-7; Figure 1). The first reading may be when the test tube P leaves the agitation area and the second reading may be at the end of the sedimentation area (page 11, lines 10-20; Figure 1).

CLAIM 46:

The continuous flexible member 1 of claim 1 may comprise elements (Figures 2-4; Figure 7) connected to one another via couplings 3A, 3B (page 21, line 16 through page 22, line 1; Figure 1; Figure 7). Consecutive elements (Figures 2-4; Figure 7) are movable with respect to one another about an axis X-X substantially parallel to a travel direction of the continuous flexible member 1 via the couplings 3A, 3B such that each of the elements (Figures 2-4; Figure 7) is rotatable about the axis X-X via at least one of the agitator devices 25 (page 24, lines 2-15; Figures 8-11). Each element 3A, 3B may comprise at least one seat for one of the test tubes P (page 20, lines 3-5; Figures 2-4). At least one of the agitator devices 25 rotate one or more of the elements (Figures 2-4; Figure 7) about the axis X-X such that blood samples contained in the test tubes P are mixed via rotation of the elements (page 24, lines 2-15; Figures 2-4; Figures 7-11).

CLAIM 47:

The agitation device 25 of claim 46 may comprise a rotor 27A, 27B and guides 39

(page 23, lines 5-6; page 23, lines 14-16; Figures 8-11). The rotor 27A, 27B is mounted for movement such that the rotor 27A, 27B rotates about the axis X-X (page 23, lines 6-9; Figures 8-11). Consecutive elements (Figures 2-4; Figure 7) move along the guides 39 and across the rotor 27A, 27B when the elements (Figures 2-4; Figure 7) are advanced along the path, whereby the consecutive elements (Figures 2-4; Figure 7) engage the guides 39 (page 24, lines 2-5; Figures 8-11). The rotor 27A, 27B rotates the elements (Figures 2-4; Figure 7) and the test tubes P held by the seats about the axis X-X (page 24, lines 2-15; Figures 8-11).

CLAIM 48:

Claim 48 is directed to an erythrocyte sedimentation rate measuring device for blood samples (Figure 1). A key feature of the device is that the holders 3 rotate about a horizontal axis (Figure 11). This allows the fluid to be mixed in a plurality of holders 3 by simply passing the holders 3 into one or more agitating devices 25 (Figures 8-11) such that one or more agitating devices rotate the holders 3 to mix the contents in the test tubes P held by the holders 3. This advantageously allows each test tube to be mixed without having to open the test tube to mix the contents contained in each test tube. This significantly increases productivity since the operating time is significantly reduced.

The device comprises a plurality of the test tubes P, each of the test tubes comprising samples of biological fluids (page 3, lines 12-18; page 20, lines 3-5; Figures 1 - 4). The device comprises the plurality of holders 3 (page 20, lines 3-5; Figures 1- 4). One of the test tubes P is inserted into at least one of the holders 3 (page 20, lines 3-5; Figures 1- 4). Each of the

holders 3 is connected to an adjacent holder to define an endless flexible member 1 (page 20, lines 1-3; Figure 1). The endless flexible member 1 is movable along a closed path (page 14, lines 6-9; page 27, lines 6-9; Figure 1). Each of the holders 3 is rotatable about a horizontal axis X-X with respect to the adjacent holder (page 24, lines 2-11; Figures 8-11). A plurality of the agitator devices 25 are provided (page 23, lines 2-4; Figures 8-11). The at least one of the agitator devices receives one or more of the holders 3 such that one or more of the holders 3 is rotated about the horizontal axis X-X (page 24, lines 2-15; Figures 8-11). The biological fluids in one or more of the holders 3 is mixed via rotation of the holders 3 (page 24, liens 2-15). The device comprises a first detector 17, a second detector 19 and a control unit 47, 275 (page 5, lines 17-20; page 20, line 16 through page 21, line 4; page 26, lines 14-16; page 36, lines 4-5; Figure 1). The agitator devices 25, the first detector 17 and the second detector 19 are arranged along the closed path (Figure 1). The first detector 17 is arranged adjacent to at least one of the agitator devices 25 (Figure 1). The second detector 19 is disposed downstream of the first detector 17 and the agitator devices 25 (Figure 1). A portion of the endless flexible member 1 extends between the first detector 17 and the second detector 19 to define a sedimentation area (page 25, lines 9-10; Figure 1). The first detector 17 detects a first level of the biological fluids in one or more holders 3 after the one or more holders 3 are rotated by the agitator devices 25 (page 20, line 16 through page 21, line 1; Figure 1). The second detector 19 detects a second level of the biological fluids in the one or more holders 3 after the one or more holders 3 are moved along the sedimentation area (page 21, lines 2-7). The control unit 47, 275 determines an erythrocyte sedimentation rate based on the first level and the second

level of the biological fluids (page 6, lines 4-10; page 40, lines 12-16).

CLAIM 49:

The at least one of the agitator devices 25 of claim 48 may rotate the one or more holders 3 between a first position (Figure 8) and a second position (Figure 11). The one or more holders 3 may be in a substantially vertical position in the first position (Figure 8). The one or more holders 3 may be in a non-vertical position in the second position (Figure 11).

CLAIM 50:

The holders 3 of claim 48 may be connected via coupling elements 3A, 3B (page 21, line 16 through page 22, line 1; Figures 2-4; Figure 7). The flexible member 1 may move in a traveling direction F1 (Figure 1). One or more of the holders 3 rotate about the horizontal axis X-X via the coupling elements 3A, 3B (page 24, lines 2-11).

CLAIM 51:

Claim 51 is directed to an erythrocyte sedimentation rate measuring device for blood samples (Figure 1). A critical features of the device is that the holders 3 rotate about a horizontal axis. This allows for the contents in the test tubes P held by the holders 3 to be mixed without each test tube having to be individually stirred as featured in conventional techniques. This significantly decreases the amount of time it takes to determine the erythrocyte sedimentation rate for the contents in each of the test tubes since the holders 3 are

able to be process more quickly than compared with conventional techniques. Further, the present invention determines the erythrocyte sedimentation rate for the blood samples, which is the rate at which red blood cells precipitate. The erythrocyte sedimentation rate is useful in diagnosing diseases, such as multiple myeloma, temporal arteritis, polymyalgia rheumatica, various auto-immune diseases, rheumatoid arthritis, chronic kidney diseases and certain inflammatory diseases.

The device comprises a plurality of test tubes P with each of the test tubes comprising samples of biological fluids (page 3, lines 12-18; page 20, lines 3-5; Figures 1 - 4). The device comprises the plurality of holders 3 (page 20, lines 3-5; Figures 1- 4). One of the test tubes P is inserted into at least one of the holders 3 (page 20, lines 3-5; Figures 1- 4). Each of the holders 3 is connected to an adjacent holder 3 to define an endless flexible member 1 (page 20, lines 1-3; Figure 1). The endless flexible member 1 is movable along a closed path (page 14, lines 6-9; page 27, lines 6-9; Figure 1). Each of the holders 3 is rotatable about a horizontal axis X-X with respect to the adjacent holder (page 24, lines 2-11; Figures 8-11). The device comprises a holder rotating means 25 for receiving one or more of the holders 3 and rotating the one or more holders about the horizontal axis X-X such that the biological fluids in the test tubes P are mixed via rotation of the holders 3 (35 U.S.C. 112, sixth paragraph; page 24, lines 2-15). The device comprises a first detector 17, a second detector 19 and a control unit 47, 275 (page 5, lines 17-20; page 20, line 16 through page 21, line 4; page 26, lines 14-16; page 36, lines 4-5; Figure 1). The holder rotating means 25, the first detector 17 and the second detector 19 are arranged along the closed path (Figure 1). The first detector 17 is arranged adjacent to

the holder rotating means 25 (Figure 1). The second detector 19 is disposed downstream of the first detector 17 (Figure 1). A portion of the endless flexible member 1 extends between the first detector 17 and the second detector 19 (Figure 1). The portion of the endless flexible member 1 defines a sedimentation area (page 25, lines 9-10; Figure 1). The first detector 17 detects a first level of the biological fluids in the one or more holders 3 after the one or more holders 3 are rotated by the holder rotating means 25 (page 20, line 16 through page 21, line 1; Figure 1). The one or more holders 3 are moved along the sedimentation area after being detected by the first detector 17 (Figure 1). The second detector 19 detects a second level of the biological fluids in the one or more holders 3 after the one or more holders 3 are moved along the sedimentation area (page 21, lines 2-7). The control unit 47, 275 determines an erythrocyte sedimentation rate based on the first level and the second level of the biological fluids (page 6, lines 4-10; page 40, lines 12-16).

CLAIM 52:

The holder rotating means 25 of claim 51 may rotate the one or more holders 3 between a first position (Figure 8) and a second position (Figure 11). The one or more holders 3 may be in a substantially vertical position in the first position (Figure 8). The one or more holders 3 may be in a non-vertical position in the second position (Figure 11).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL.

Whether claims 1-11, 13-17, 21-28, 41 - 44 and 46-52 are rejectable under 35 U.S.C.

102(b) as being anticipated by Skotnikov et al. (US 5,526,705).

Whether claims 18-20 are rejectable under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Kaarkainen et al. (US 6,520,313).

Whether claims 29, 30 and 32-34 are rejectable under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Coulter et al. (US 4,609,017).

Whether claim 31 is rejectable under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Coulter et al. and in further view of Roginski (US 4,927,545).

(7) ARGUMENT.

ISSUE: Whether claims 1-11, 13-17, 21-28, 41 - 44 and 46-52 are rejectable under 35 U.S.C. 102(b) as being anticipated by Skotnikov et al. (US 5,526,705).

CLAIM 1

The present invention relates to an erythrocyte sedimentation rate measuring device for blood samples. The device includes at least two detectors and agitating devices. The agitating devices rotate holders that hold test tubes containing biological fluids, such as blood. The two detectors measure the level of the fluid in the test tubes. A control unit can advantageously determine an erythrocyte sedimentation rate of the fluids based on the levels of the fluid detected by the two detectors. This advantageously does not produce any liquid or solid waste since separate tubes do not have to be used to draw a sample of the blood to determine the

erythrocyte sedimentation rate. The prior art as a whole fails to teach and fails to suggest such features or such waste saving advantages.

Skotnikov et al. discloses an apparatus that analyzes a plurality of soil samples to determine characteristics of the soil samples. An input portion sequentially provides a plurality of soil samples each having a known solid content. A plurality of vessels are supported for movement with a continuous conveyor relative to the input portion to receive the soil samples. A plurality of testing stations are arranged relative to the continuous conveyor to sequentially access the samples carried by the vessels. The testing stations each test the samples to determine at least one of the characteristics of the samples.

Skotnikov et al. fails to teach and fails to suggest the combination of a first detector and a second detector that detect levels of fluid in test tubes in holders after the fluid is shaken by agitating devices. According to the present invention, the first detector and the second detector are spaced apart from each other via a sedimentation area and a control unit determines an erythrocyte sedimentation rate of the fluid based on the levels detected by the two detectors. At most, Skotnikov et al. discloses testing stations that test soil samples to determine at least one of the characteristics of the samples. However, Skotnikov et al. does not provide any teaching or suggestion for any of the testing stations measuring a level of fluid in a test tube that is held by a holder wherein the control unit determines an erythrocyte sedimentation rate as claimed. The final rejection takes the position that the stations A, B, C, D, F, G, H and J of Skotnikov et al. are provided with detectors. While it is true that Skotnikov et al. discloses various detectors for detecting different properties of <u>soil</u>, there is no teaching or suggestion

in Skotnikov et al. that would direct a person of ordinary skill in the art toward two detectors that measure a level of biological fluids in test tubes that are moved along a closed path as claimed. Skotnikov et al. only discloses detectors at various stations that determine soil acidity, soil carbon content, determination of nutrients and micronutrients, alkali soluble fraction of organic matters and the determination of dust, sand and physical clay in the sample. This does not allow the erythrocyte sedimentation rate to be determined based on such detected characteristics. The detection of the level of fluid in the test tubes is a significant feature of the present invention because the erythrocyte sedimentation rate is determined based on the detected levels of the fluid. Skotnikov et al. fails to disclose such erythrocyte sedimentation rate determining features. Skotnikov et al. does not teach any sedimentation analysis or provide a teaching of features to provide such analysis. In fact, Skotnikov et al. does not teach or suggest any measuring arrangement based on detection of levels measured at two positions spaced apart from one another by a sedimentation area as claimed. Skotnikov et al. only discloses that tests are performed at various testing stations, but Skotnikov et al. does not teach or suggest a control unit that determines a sedimentation rate by comparing data detected at two sequentially arranged spaced apart detection stations as featured in the present invention. As such, the prior art as a whole does not teach or suggest important features of the claimed combination.

The final rejection takes the position that the recitation in the preamble for measuring sedimentation rate in biological samples has not been given patentable weight. Appellant understands that recitations in preambles are not given patentable weight. However, clear

limitations recited in the claims are given patentable weight. Claim 1 clearly provides that the control unit determines the erythrocyte sedimentation rate based on detection of fluid levels by two detectors. There is no teaching or suggestion for this limitation in Skotnikov et al. as Skotnikov et al. is not concerned with determining an erythrocyte sedimentation rate as claimed. Accordingly, the rejection should be reversed with respect to claim 1 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 2

Skotnikov et al. does not teach and does not suggest the combination of agitator devices that oscillate holders such that fluid in the holders is stirred. The final rejection takes the that stirrer 100 of Skotnikov et al. is the equivalent of one of the agitating devices of the present invention. Appellant respectfully disagrees with this interpretation of Skotnikov et al. The stirrer 100 of Skotnikov et al. does not oscillate the vessel 32 as required by the claimed combination. Although Skotnikov et al. discloses that the <u>contents</u> of the vessel 32 are agitated by the stirrer 100, the stirrer 100 does not move the vessel 32 up and down or back and forth as featured in the present invention. Skotnikov et al. only discloses that the stirrer 100 is inserted into the vessel 32 and the contents of the vessel 32 are stirred. This is completely different than oscillating the vessel 32 as claimed. The oscillation of the holders by the agitator devices is a critical feature of the present invention because it allows multiple holders to be moved at once so the overall operating productivity can be significantly increased. This is very

different from Skotnikov et al. since each test tube does not have to be individually stirred as taught by Skotnikov et al. Also such stirring involves insertion of a stirrer 100 in the vessel 32, thereby also requiring a cleaning or sanitizing. As such, the prior art as a whole does not teach or suggest each and every feature of the claimed combination. Accordingly, the rejection should be reversed with respect to claim 1 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 3

Skotnikov et al. does not provide any teaching or suggestion for any of the testing stations measuring a level of fluid in a test tube that is held by a holder as claimed. The final rejection takes the position that reference numeral 78 of Skotnikov et al. is the equivalent of at least one of the detectors of the present invention. Appellant respectfully disagrees as reference numeral 78 of Skotnikov et al. relates to an automated photo-electric calorimeter 78. The calorimeter 78 of Skotnikov et al. only measures the heat created during a reaction and does not measure a level of a fluid in a test tube as claimed. The detection of the level of fluid in the test tubes is a significant feature of the present invention because the erythrocyte sedimentation rate is determined based on the detected levels of the fluid. Skotnikov et al. fails to disclose such erythrocyte sedimentation rate determining features. Accordingly, the rejection should be reversed with respect to claim 3 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 4

Skotnikov et al. fails to teach or suggest the combination of a continuous flexible member defining a closed path, wherein a first detector and a second detector are arranged in sequence along the path with the detectors detecting a level of fluid in the test tubes held by the holders of the flexible member as claimed. The final rejection takes the position that the continuous conveyor 36 of Skotnikov et al. is the equivalent of the continuous flexible member of the present invention. Appellant respectfully disagrees with this interpretation of Skotnikov et al. Besides the fact that no biological level detecting detectors are arranged along the continuous conveyor 36 of Skotnikov et al., there is no teaching or suggestion that the continuous conveyor 36 is flexible as required in the claimed combination. The flexibility of the continuous member is an important feature of the claimed combination since it allows the holders to rotate about a horizontal axis when the agitating devices move the holders. Skotnikov et al. does not teach or suggest that the conveyor 36 is flexible as claimed. Accordingly, the rejection should be reversed with respect to claim 4 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 5

Skotnikov et al. fails to teach or suggest the combination of a continuous flexible member defining a closed path, wherein a control unit determines an erythrocyte sedimentation rate based on a level of biological fluid detected by a first detector and a second detector are

arranged in sequence along the path as claimed. In addition to Skotnikov et al. not teaching or suggesting a control unit that determines an erythrocyte sedimentation rate, there is no teaching or suggestion in Skotnikov et al. that the continuous conveyor 36 is flexible as required in the claimed combination. The flexibility of the continuous member of the present invention advantageously allows the holders of the present invention to move back and forth when they reach the agitating devices. Skotnikov et al. does not teach or suggest that the conveyor 36 is flexible as claimed. Accordingly, the rejection should be reversed with respect to claim 5 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 6

Skotnikov et al. does not provide any teaching or suggestion for elements that are interconnected wherein each of the elements comprise a single seat for receiving a test tube having biological fluid therein as claimed. At most, Skotnikov et al. discloses vessels 32 that contain soil samples and not biological fluid as claimed. Skotnikov et al. does not provide any teaching or suggestion that the vessels 32 are test tubes as featured in the present invention. Accordingly, the rejection should be reversed with respect to claim 6 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 7

Skotnikov et al. fails to teach or suggest the combination of agitator devices that rotate one or more of holders about a horizontal axis as featured in the present invention. Although Skotnikov et al. discloses that agitators 40 agitate the contents of a vessel 32, there is no teaching and no suggestion that the agitators 40 rotate the vessel 32 as required in the claimed combination. Claim 7 provides a very specific definition of how the test tubes are stirred. Claim 7 requires that each holder is mounted for movement such that each holder is rotatable with respect to an adjacent holder about a horizontal axis that is parallel to the traveling direction of the flexible chain member. Such features are not disclosed in Skotnikov et al. In fact, a fair reading of Skotnikov et al. discloses that a stirrer 100 is used to agitate the soil sample in the vessel wherein the stirrer moves up and down in a vertical direction in the vessel 32. This contaminates the stirrer 100. The present invention takes a completely different approach by rotating the holders with the agitator devices. This is clearly not taught nor suggested by Skotnikov et al. Accordingly, the rejection should be reversed with respect to claim 7 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 8

Skotnikov et al. fails to provide any teaching or suggestion for the combination of couplings that are composed of spherical joints wherein the elements that are interconnected to form a flexible chain member are coupled together via the spherical joints. Skotnikov et al.

merely discloses a conveyor 36 formed of a two-strand plastic link belt or a disk or other suitable conveyor. According to Skotnikov et al. The links in the belt are sized to snugly fit about an outer perimeter of vessels 32. However, there is no teaching and no suggestion that the links of Skotnikov et al. are coupled together via spherical joints as featured in the present invention. The spherical joints are important in the present invention because they allow the holders to rotate about a horizontal axis via agitating devices. This allows the biological fluid in the test tubes to be mixed without having to individually stir the contents of each test tube. Skotnikov et al. fails to teach or suggest the advantages of using spherical joints since the vessels 32 of Skotnikov et al. are not rotatable as claimed. There is simply no teaching or suggestion in Skotnikov et al. that would direct a person of ordinary skill in the art toward spherical joints that connect elements to form a flexible chain member as claimed. Accordingly, the rejection should be reversed with respect to claim 8 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 9

There is no teaching or suggestion in Skotnikov et al. for the combination of elements that form a flexible chain member, that are oscillated, such that at least one holder rotates about a horizontal axis as claimed. Skotnikov et al. only discloses an agitator 40, 50, 100 that agitates the contents of a vessel 32. There is no teaching or suggestion in Skotnikov et al. that the agitator 40, 50, 100 rotates the vessel 32 about a horizontal axis to mix the soil sample in

the vessel 32 as claimed. Claim 9 requires that at least one holder is rotated about a horizontal axis. This is clearly not taught or suggested by the disclosure of Skotnikov et al. Accordingly, the rejection should be reversed with respect to claim 9 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 10

Skotnikov et al. fails to teach and fails to suggest the combination of elements of holders that engage guides of at least one agitator device wherein the agitator device rotates at least one holder about a horizontal axis via the guides as claimed. The final rejection takes the position that sprockets 140 of Skotnikov et al. are the equivalent of the guides of the present invention. However, sprockets 140 of Skotnikov et al. only moves the conveyor 36. The sprockets of Skotnikov et al. do not aid in rotating the vessels 32 as featured in the present invention. In fact, Skotnikov et al. does not provide any teaching or suggestion that the vessels 32 are rotated about a horizontal axis as featured in the present invention. Compared with Skotnikov et al., one or more holders of the present invention is rotated by an agitating device about a horizontal axis. This advantageously allows the biological fluid in the one or more holders to be mixed without opening the test tube and stirring the contents of the test tube as taught by Skotnikov et al. With the invention, nothing is inserted into the sample. In contrast to the present invention, Skotnikov et al. only directs a person of ordinary skill in the art toward stirring or agitating the soil sample in a vessel 32, but this does not provide any teaching or suggestion for rotating the vessel 32 with an agitating device as claimed.

Accordingly, the rejection should be reversed with respect to claim 10 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 11

Claim 11 requires that the elements that form a continuous flexible chain member comprise sliding shoes that engage guides of agitating devices wherein the agitating devices rotate the elements so that at least one holder is rotated about a horizontal axis. The final rejection takes the position that the conveyor holders can be viewed as sliding shoes as featured in the present invention and that the sprockets 140 form the guides of the agitating devices. Appellant disagrees with this interpretation as the sprockets 140 are not part of the agitating devices 40, 50, 100. Even if the sprockets 140 of Skotnikov et al. could somehow be the equivalent of the guide of an agitating device, there is no teaching or suggestion in Skotnikov et al. that the sprockets 140 aid in rotating one or more vessels 32 as featured in the present invention. Skotnikov et al. simply does not teach or suggest an arrangement in which guides of an agitating device contact sliding shoes of elements of at least one holder such that the at least holder is rotated as featured in the present invention. Accordingly, the rejection should be reversed with respect to claim 11 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 13

Skotnikov et al. fails to teach and fails to suggest the combination of mobile guides of agitator devices that extend along a portion of the path covered by a continuous flexible chain member wherein the mobile guides rotate at least one holder about a horizontal axis as claimed. Skotnikov et al. only discloses agitators 40, 50, 100. However, the agitators 40, 50, 100 of Skotnikov et al. do not have mobile guides that extend along a portion of the conveyor 36 to rotate the vessels 32 as featured in the present invention. Skotnikov et al. only discloses agitating the soil samples in each vessel 32 by inserting a stirrer 100 into one of the vessels and agitating the soil sample in the vessel 32 with the stirrer 100. This does not provide any teaching or suggestion as to rotating one or more holders so that the one or more holders rotate about a horizontal axis as claimed. Accordingly, the rejection should be reversed with respect to claim 13 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 14

Skotnikov et al. does not provide any teaching or suggestion for the combination of agitator devices that comprise a rotor that is coaxial with a portion of a path of a flexible member wherein the rotor is provided with engaging elements for engaging holders that come along a portion along the path of the flexible member as featured in the present invention. The final rejection takes the position that the agitating devices 40, 50, 100 of of Skotnikov et al. comprise sprockets 140, which are the equivalent of the rotor of the present invention. This

is not consistent with the teachings and suggestions of Skotnikov et al. The sprockets 140 of Skotnikov et al. do not form a part of the agitating devices 40, 50, 100. As such, the sprockets 140 are not the equivalent of the rotor of the present invention since the agitator devices of the present invention comprise the rotor. Even if the sprockets 140 of Skotnikov et al. could somehow be the equivalent of the rotor of the present invention, the sprockets 140 are not coaxial with a portion of the path of the conveyor 36 as claimed. Accordingly, the rejection should be reversed with respect to claim 14 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 15

Skotnikov et al. does not teach or suggest the combination of engaging elements of agitator devices in the form of guides with holders slidingly engaging the guides wherein the agitator devices rotate at least one of the holders about a horizontal axis as claimed. Skotnikov et al. clearly teaches that the vessels 32 remain in a fixed position when the stirrer is inserted into the vessels 32 to stir the soil samples contained in the vessels 32. Skotnikov et al. simply does not provide any teaching or suggestion for rotating the vessels 32 to mix the soil samples in the vessels 32 as claimed. Accordingly, the rejection should be reversed with respect to claim 15 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 16

Skotnikov et al. does not teach or suggest the combination of a first detector arranged along a closed path, downstream from agitator devices, and a second detector arranged further along the path, downstream from a portion of path defining a sedimentation area wherein the detectors detect a level of biological fluid in test tubes as claimed. Although Skotnikov et al. discloses a plurality of detectors that determine various characteristics of soil samples, none of the detectors in Skotnikov et al. detect levels of biological fluid in test tubes as claimed. In fact, Skotnikov et al. does not teach or suggest a sedimentation area as claimed. Compared with Skotnikov et al., the first detector and the second detector are spaced apart from one another via a sedimentation area. The sedimentation area allows the biological fluid in the test tubes to settle after the test tubes are mixed by the agitator devices. Skotnikov et al. does not teach or suggest a first detector spaced apart from a second detector via a sedimentation area as claimed. Skotnikov et al. clearly discloses that the various detectors are separated by different stations at which tests are performed on the soil samples in the vessels 32. As such, the prior art as a whole takes a completely different approach and fails to teach or suggest important features of the claimed combination. Accordingly, the rejection should be reversed with respect to claim 16 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 17

Skotnikov et al. does not teach or suggest the combination of a third detector arranged

downstream from a portion of a closed path that defines a second sedimentation area as claimed. Skotnikov et al. only discloses that vessels 32 are passed from one station to another station wherein different tests are conducted on the soil samples contained in the vessels 32 to determine different characteristics of the soil samples. However, there are not two sedimentation areas in the arrangement of Skotnikov et al. The sedimentation areas of the present invention provide an area of the closed path in which the holders are passed along with the test tubes so that the biological fluid in the test tubes settle so that the level of the biological fluid after agitation can be detected. Skotnikov et al. does not disclose detectors that detect levels of biological fluid in test tubes and any sedimentation areas as claimed. Accordingly, the rejection should be reversed with respect to claim 17 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 21

Skotnikov et al. fails to teach or suggest the combination of a first detector and a second detector that determine levels of biological fluid in test tubes wherein at least one extractor removes the test tubes from holders as claimed. Although Skotnikov et al. discloses various detectors to detect different soil properties of the soil samples contained in vessels 32, there is no teaching or suggestion in Skotnikov et al. for the detectors detecting levels of biological fluids as claimed. In fact, Skotnikov et al. does not teach or suggest the combination of a control unit that determines an erythrocyte sedimentation rate as featured in Appellant's invention. Accordingly, the rejection should be reversed with respect to claim 21 as the prior

art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 22

Skotnikov et al. does not teach or suggest the combination of two extractors that remove test tubes from holders and distributes the test tubes in respective containers as claimed. Although Skotnikov et al. does teach a washer 104 and dryer 106 can be a robotic manipulator that injects water into vessels 32, removes vessels 32 from conveyor 36 to dump out water, replaces vessels 32 in conveyor 36 and heats vessels 32 to dry them, Skotnikov et al. does not disclose that the robotic manipulator removes the vessels 32 and distributes them to containers as claimed. As such, the prior art as a whole takes a different approach and fails to teach or suggest each and every feature of the claimed combination. Accordingly, the rejection should be reversed with respect to claim 22 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 23

Skotnikov et al. does not teach or suggest the combination of automatic manipulators that automatically insert test tubes in holders wherein the levels of biological fluids in the test tubes are detected by two detectors as claimed. Although Skotnikov et al. discloses various detectors to detect different soil properties of the soil samples contained in vessels 32, there is no teaching or suggestion in Skotnikov et al. for the detectors detecting levels of biological

fluids as claimed. In fact, Skotnikov et al. does not teach or suggest the combination of a control unit that determines an erythrocyte sedimentation rate as featured in Appellant's invention. Accordingly, the rejection should be reversed with respect to claim 23 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 24

Skotnikov et al. does not provide any teaching or suggestion for the combination of manipulators that move single test tubes from a rack of test tubes and insert the test tubes in holders that form a continuous flexible chain member as claimed. Although Skotnikov et al. discloses a washer 104 and dryer 106 can be a robotic manipulator that injects water into vessels 32, removes vessels 32 from conveyor 36 to dump out water, replaces vessels 32 in conveyor 36 and heats vessels 32 to dry them, Skotnikov et al. does not disclose that the robotic manipulator moves single test tubes from a rack of test tubes and inserts the test tubes in holders that form a continuous flexible chain member as claimed. Skotnikov et al. clearly is not concerned with moving a plurality of test tubes from a rack and inserting each test tube in a respective holder as claimed. As such, the prior art as a whole takes a different approach and fails to teach or suggest each and every feature of the claimed combination. Accordingly, the rejection should be reversed with respect to claim 24 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 25

Skotnikov et al. does not teach or suggest the combination of a setup unit that prepares test tubes for insertion in holders wherein levels of the biological fluids in the test tubes are detected by two detectors as claimed. Although Skotnikov et al. discloses various detectors to detect different soil properties of the soil samples contained in vessels 32, there is no teaching or suggestion in Skotnikov et al. for the detectors detecting levels of biological fluids as claimed. In fact, Skotnikov et al. does not teach or suggest the combination of a control unit that determines an erythrocyte sedimentation rate as featured in Appellant's invention. Accordingly, the rejection should be reversed with respect to claim 25 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 26

Skotnikov et al. fails to provide any teaching or suggestion for the combination of a setup unit that is situated above a continuous flexible member as claimed. Skotnikov et al. only discloses a soil preparation line 12 that includes an unpacking unit 20, mixing chamber 22, water valve 24, filter 26, humidity meter 28 and volume doser 30. However, the soil preparation line 12 of Skotnikov et al. is not situated above a continuous flexible member as featured in the present invention. Figure 1 of Skotnikov et al. clearly shows that the soil preparation line 12 is located at a position lateral to the conveyor 36. Compared with Skotnikov et al., the setup unit is situated above the continuous flexible member so that the test

tubes can be dropped down into the holders that form the continuous flexible member. In contrast to the present invention, the soil preparation line 12 is not positioned above a continuous flexible member as featured in the present invention. Accordingly, the rejection should be reversed with respect to claim 26 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 27

Skotnikov et al. does not teach and does not suggest the combination of a setup unit that comprises a reading station that automatically reads labels attached to test tubes as claimed. The final rejection relies on Column 3, lines 45-52 of Skotnikov et al. to teach a reading station that reads labels attached to test tubes as featured in the present invention. Appellant respectfully disagrees with this interpretation of Skotnikov et al. Column 3, lines 45-52 of Skotnikov et al. only disclose that the soil samples withdrawn from mixing chamber 22 are provided in a humidity meter 28 long enough for a controller to take a number of humidity measurements. This has nothing to do with reading a label on test tubes as claimed in claim 27. The reading of the labels on test tubes of the present invention advantageously provides a determination of which test tubes must undergo a measurement of the sedimentation rate of the sample contained in the test tubes. Column 3, lines 45-52 of Skotnikov et al. does not make any mention of reading labels of test tubes at a reading station as claimed. Accordingly, the rejection should be reversed with respect to claim 27 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C.

102(b) rejection.

CLAIM 28

Skotnikov et al. fails to teach or suggest the combination of manipulators that controlled and operated by a central unit as a function of information provided for each test tube by reading stations wherein the manipulators transfer the test tubes in which the sedimentation rate must be measured from the rack to a corresponding holder as claimed. The final rejection relies on Column 3, lines 45-52 of Skotnikov et al. to teach manipulators that are controlled as a function of information provided from reading stations. Column 3, lines 45-52 of Skotnikov et al. only disclose that the soil samples withdrawn from mixing chamber 22 are provided in a humidity meter 28 long enough for a controller to take a number of humidity measurements. This has nothing to do with controlling a manipulator based on information from a reading station as claimed in claim 28. Accordingly, the rejection should be reversed with respect to claim 28 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 41

Skotnikov et al. does not teach and does not suggest the combination of agitator devices and a sedimentation area arranged along a closed path of the continuous flexible member wherein the agitator devices oscillate holders such that fluid in the holders is stirred as claimed. Skotnikov et al. only discloses that the soil samples of the vessels 32 are agitated. However,

the agitating devices 40, 50, 100 of Skotnikov et al. does not oscillate the vessel 32 as required by the claimed combination. Although Skotnikov et al. discloses that the <u>contents</u> of the vessel 32 are agitated by the agitating devices 40, 50, 100, the agitating devices 40, 50, 100 do not move the vessel 32 up and down or back and forth as featured in the present invention. Skotnikov et al. only discloses that the stirrer 100 is inserted into the vessel 32 and the contents of the vessel 32 are stirred. This is completely different than oscillating the vessel 32 as claimed. The oscillation of the holders by the agitator devices is a critical feature of the present invention because it allows multiple holders to be moved at once so the overall operating productivity can be significantly increased. This is very different from Skotnikov et al. since each test tube does not have to be individually stirred by a stirrer within the vessel as taught by Skotnikov et al. (Column 6, line 52). As such, the prior art as a whole does not teach or suggest each and every feature of the claimed combination. Accordingly, the rejection should be reversed with respect to claim 41 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 42

Skotnikov et al. fails to teach or suggest the combination of a continuous flexible member defining a closed path lying substantially on a horizontal plane, wherein a first detector and a second detector are arranged in sequence along the path with the detectors detecting a level of fluid in the test tubes held by the holders of the flexible member as claimed. The final rejection takes the position that the continuous conveyor 36 of Skotnikov

et al. is the equivalent of the continuous flexible member of the present invention. Appellant respectfully disagrees with this interpretation of Skotnikov et al. Besides the fact that no biological level detecting detectors are arranged along the continuous conveyor 36 of Skotnikov et al., there is no teaching or suggestion that the continuous conveyor 36 is flexible as required in the claimed combination. The flexibility of the continuous member is an important feature of the claimed combination since it allows the holders to rotate about a horizontal axis when the agitating devices move the holders. Skotnikov et al. does not teach or suggest that the conveyor 36 is flexible as claimed. Accordingly, the rejection should be reversed with respect to claim 4 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 43

Skotnikov et al. does not provide any teaching or suggestion for two detectors that measure levels of biological fluid in test tubes held by holders wherein at least one of the detectors is arranged in a reading area along a closed path of a continuous flexible member as claimed. Skotnikov et al. does not disclose that any of the testing stations measuring a level of fluid in a test tube that is held by a holder as claimed. The final takes the position that reference numeral 78 of Skotnikov et al. is the equivalent of at least one of the detectors of the present invention. Appellant respectfully disagrees as reference numeral 78 of Skotnikov et al. relates to an automated photo-electric calorimeter 78. The calorimeter 78 of Skotnikov et al. only measures the heat created during a reaction and does not measure a level of a fluid in

a test tube as claimed. The detection of the level of fluid in the test tubes is a significant feature of the present invention because the erythrocyte sedimentation rate is determined based on the detected levels of the fluid. Skotnikov et al. fails to disclose such erythrocyte sedimentation rate determining features. Accordingly, the rejection should be reversed with respect to claim 3 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 44

Skotnikov et al. fails to teach or suggest the combination of elements interconnected to form a continuous flexible member defining a closed path, wherein a control unit determines an erythrocyte sedimentation rate based on a level of biological fluid detected by a first detector and a second detector are arranged in sequence along the path as claimed. In addition to Skotnikov et al. not teaching or suggesting a control unit that determines an erythrocyte sedimentation rate, there is no teaching or suggestion in Skotnikov et al. that the continuous conveyor 36 is flexible as required in the claimed combination. The flexibility of the continuous member of the present invention advantageously allows the holders of the present invention to move back and forth when they reach the agitating devices. Skotnikov et al. does not teach or suggest that the conveyor 36 is flexible as claimed. Accordingly, the rejection should be reversed with respect to claim 44 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 46

Skotnikov et al. fails to provide any teaching or suggestion for the combination of a continuous flexible member that comprises elements connected to one another via couplings wherein the elements are rotatable about an axis substantially parallel to a travel direction of the continuous flexible member as claimed. Skotnikov et al. merely discloses agitating the contents (soil samples) of the vessel 32. This does not provide any teaching or suggestion as to rotating the vessel 32 about an axis substantially parallel to a travel direction of the conveyor 36 as claimed. Compared with Skotnikov et al., the elements of the holders are rotated by agitating devices. This advantageously allows for several holders to be rotated at the same time. This saves a significant amount of operating time since each test tube does not have to be individually agitated as disclosed in Skotnikov et al. Compared with the present invention, Skotnikov et al. discloses agitating devices 40, 50 and 100, but none of the agitating devices 40, 50 and 100 rotate the vessels 32 as required in the claimed combination. Accordingly, the rejection should be reversed with respect to claim 46 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 47

Skotnikov et al. does not teach or suggest the combination of agitation devices that comprises a rotor that rotates elements of holders and test tubes held by the holders about an axis that is substantially parallel to a traveling direction of a continuous flexible member as featured in the present invention. The final rejection takes the position that the agitating

devices 40, 50, 100 of of Skotnikov et al. comprise sprockets 140, which are the equivalent of the rotor of the present invention. This is not consistent with the teachings and suggestions of Skotnikov et al. The sprockets 140 of Skotnikov et al. do not form a part of the agitating devices 40, 50, 100. As such, the sprockets 140 are not the equivalent of the rotor of the present invention since the agitator devices of the present invention comprise the rotor. Even if the sprockets 140 of Skotnikov et al. could somehow be the equivalent of the rotor of the present invention, the sprockets 140 do not rotate the vessels 32 about an axis that is substantially parallel to the travel direction of the conveyor 36 as claimed. Accordingly, the rejection should be reversed with respect to claim 47 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 48

Claim 48 provides a control unit, a first detector that detects a fluid level in the test tubes after the test tubes are agitated, a second detector that detects a fluid level in the test tubes after the test tubes have passed a sedimentation area and agitator devices that rotate the test tubes. Each of these features are not disclosed in Skotnikov et al. These features provide a particular arrangement that allows the erythrocyte sedimentation rate of the fluid in the test tubes to be accurately determined so that a patient can be properly diagnosed.

The final rejection takes the position that recitations provided in the preamble of a claim are not given patentable weight and accordingly measuring sedimentation rate in biological samples and especially in blood samples is not given patentable weight. However,

claim 48 clearly requires the limitation of a control unit that determines an erythrocyte sedimentation rate based on fluid levels of biological fluids in test tubes. Such a control unit is clearly not disclosed in Skotnikov et al. since Skotnikov et al. is only concerned with determining various soil characteristics of soil samples in vessels 32. This is a much different approach than that of the present invention. In the present invention, the erythrocyte sedimentation rate is determined with a control unit. The erythrocyte sedimentation rate is useful in diagnosing a patient and is particularly useful for determining whether a patient has inflammatory diseases, such as rheumatoid arthritis. Skotnikov et al. clearly does not direct a person of ordinary skill in the art toward determining the erythrocyte sedimentation rate since Skotnikov et al. is only concerned with determining different properties of soil samples and is not concerned with analyzing the soil to determine an erythrocyte sedimentation rate as claimed.

Skotnikov et al. does not teach or suggest the combination of a portion of an endless flexible member extending between a first detector and a second detector that defines a sedimentation area. The holders are moved along the sedimentation area of the present invention so that the fluid in the test tubes is allowed to settle after the test tubes are agitated by the agitation devices. Skotnikov et al. discloses that vessels are moved from one station to the next, but there is no teaching or suggestion that the vessels move along a sedimentation area as claimed. The sedimentation area is essential to the determination of the erythrocyte sedimentation rate since the determination is based on the level of fluid just after the fluid is agitated and on the level fluid after the test tubes have settled as the test tubes pass along the

sedimentation area. No such sedimentation area exists in Skotnikov et al.

Skotnikov et al. fails to disclose at least one agitator device that rotates one or more holders rotated about a horizontal axis as claimed. Although Skotnikov et al. discloses various agitating devices 40, 50 and 100, none of the agitating devices 40, 50 and 100 rotate the vessels 32 as claimed. Skotnikov et al. only discloses that a stirrer is inserted into the vessels 32 and moved vertically in an upward and downward direction within the vessel to agitate the soil samples contained in the vessels 32. This is a very different approach that does not allow for the possibility of a plurality of holders to be mixed at one time as featured in the present invention. Compared with Skotnikov et al., the agitator devices rotate one or more holders about an axis to mix the contents in the test tubes that are held by the holders. This advantageously allows for more than one holder to be mixed at a time. Skotnikov et al. does not disclose such operating time reduction advantages since Skotnikov et al. is completely void of any teaching or suggestion that the agitating devices 40, 50 and 100 that rotate the vessels 32 about an axis as claimed.

Skotnikov et al. fails to teach or suggest the combination of a first detector that detects a first level of biological fluids in one or more holders after the one or more holders has been rotated and a second detector that detects a second level of the biological fluids in the one or more holders after the one or more holders are moved along a sedimentation area as claimed. Skotnikov et al. only discloses a plurality of different stations having different detectors for determining various soil sample properties. However, none of the detectors disclosed in Skotnikov et al. have anything to do with detecting a level of fluid in the vessels 32 as featured

in the present invention. The detection of the biological fluid in the test tubes is critical to the present invention because it allows for the determination of the erythrocyte sedimentation rate. Skotnikov et al. fails to be teach or suggest that any of the detectors detect any levels of biological fluid in the vessels 32 to determine an erythrocyte sedimentation rate as claimed. Accordingly, the rejection should be reversed with respect to claim 48 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 49

Claim 49 provides that the holders are rotated between a substantially vertical position and a non-vertical position by at least one agitator device. Such a combination of features is not disclosed in Skotnikov et al. since Skotnikov et al. does not provide any teaching or suggestion that the agitator devices 40, 50 and 100 rotate the vessels 32 as featured in the present invention. Skotnikov et al. only discloses that the agitator devices 40, 50 and 100 agitate the contents of vessels 32 by inserting a stirrer. As such, the prior art as a whole takes a completely different approach from that of the present invention. Accordingly, the rejection should be reversed with respect to claim 49 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 50

Skotnikov et al. does not provide any teaching or suggestion for the combination of one

or more holders that are connected by coupling elements and are rotated about a horizontal axis via at least one agitator as claimed. There is simply no teaching or suggestion in Skotnikov et al. that would direct a person of ordinary skill in the art toward rotating the vessels with agitator devices 40, 50 and 100. Accordingly, the rejection should be reversed with respect to claim 50 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 51

Claim 51 provides the combination of a control unit, a portion of an endless flexible member that defines a sedimentation area, a first detector that detects a first level of biological fluids in one or more holders after the one or more holders are rotated by a holder rotating means and a second detector that detects a second level of the biological fluids in the one or more holders after the one or more holders are moved along the sedimentation area. Each of these features of this arrangement is neither taught nor suggested by Skotnikov et al. The arrangement of the detectors, sedimentation area, holder rotating means and control unit allows the erythrocyte sedimentation rate of the biological fluids in the test tubes to be accurately determined. Further, the holder rotating means advantageously allows more than one test tube to be rotated at a time. This significantly decreases the overall operating time of the erythrocyte sedimentation rate determining process so that more test tubes can be tested than conventional techniques.

The determination of the erythrocyte sedimentation rate is not merely a recitation in the

preamble as stated in the final rejection. Claim 51 requires that the control unit determines the erythrocyte sedimentation rate, which is critical in determining whether a patient has a particular disease. Skotnikov et al. does not teach or suggest the combination of a control unit that determines an erythrocyte sedimentation rate as claimed. Skotnikov et al. only discloses various stations that determine various properties of soil samples in vessel 32. As such, the prior art does not teach or suggest critical features of the present invention.

Skotnikov et al. does not provide any teaching or suggestion for the combination of a first detector that detects a first level of biological fluids in one or more holders after the one or more holders are rotated by a holder rotating means and a second detector that detects a second level of the biological fluids in the one or more holders after the one or more holders are moved along the sedimentation area. Skotnikov et al. only discloses a plurality of station with each station having a particular detector for determining different characteristics of the soil samples. None of the detectors of Skotnikov et al. detect a level of biological fluid in the vessels 32. This does not allow the erythrocyte sedimentation rate to be determined in Skotnikov et al. As such, the prior art as a whole does not teach or suggest important features of the present invention.

Skotnikov et al. does not teach and does not suggest the combination including a holder rotating means that rotates at least one holder about an axis as claimed. The final rejection takes the position that stirrer 100 of Skotnikov et al. is the equivalent of one of the agitating devices of the present invention. Appellant respectfully disagrees with this interpretation of Skotnikov et al. The stirrer 100 of Skotnikov et al. does not rotate the vessel 32 as required

by the claimed combination. Although Skotnikov et al. discloses that the <u>contents</u> of the vessel 32 are agitated by the stirrer 100, the stirrer 100 does not rotate the vessel 32 as featured in the present invention. Skotnikov et al. only discloses that the stirrer 100 is <u>inserted into the vessel</u> 32 and <u>the contents</u> of the vessel 32 <u>are stirred</u>. This is completely different than rotating the vessel 32 as claimed. The rotation of the holders by the agitator devices is a critical feature of the present invention because it allows multiple holders to be moved at once so the overall operating productivity can be significantly increased. It avoids the problem of contaminating stirrers or samples or the need to clean stirrers. This is very different from Skotnikov et al. since each test tube does not have to be individually stirred as taught by Skotnikov et al. As such, the prior art as a whole does not teach or suggest each and every feature of the claimed combination. Accordingly, the rejection should be reversed with respect to claim 51 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CLAIM 52

Claim 52 provides that the holders are rotated between a substantially vertical position and a non-vertical position by at least one agitator device. Such a combination of features is not disclosed in Skotnikov et al. since Skotnikov et al. does not provide any teaching or suggestion that the agitator devices 40, 50 and 100 rotate the vessels 32 as featured in the present invention. Skotnikov et al. only discloses that the agitator devices 40, 50 and 100 agitate the contents of vessels 32 by inserting a stirrer. As such, the prior art as a whole takes

a completely different approach from that of the present invention. Accordingly, the rejection should be reversed with respect to claim 52 as the prior art as a whole does not teach or suggest each and every feature claimed as required in a 35 U.S.C. 102(b) rejection.

CONCLUSION

The cited prior art references fail to teach or suggest the crux of the invention. The invention presents a novel combination of features. The prior art fails to teach or suggest each and every feature of the structural combination as claimed. Accordingly, it is requested that the Examiner's rejections be reversed.

ISSUE: Whether claims 18-20 are rejectable under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Kaarkainen et al. (US 6,520,313).

CLAIMS 18, 19 AND 20

Skotnikov et al. and Kaarkainen et al. fail to teach and fails to suggest the combination of a first detector and a second detector that detect levels of fluid in test tubes in holders after the fluid is shaken by agitating devices. According to the present invention, the first detector and the second detector are spaced apart from each other via a sedimentation area and a control unit determines an erythrocyte sedimentation rate of the fluid based on the levels detected by the two detectors. At most, Skotnikov et al. discloses testing stations that test soil samples to determine at least one of the characteristics of the samples and Kaarkainen et al. discloses test

tubes 1 that are placed on transport bases 3 for transportation within a system and the identification data of the test tube 1 is read to identify the sample. However, Skotnikov et al. and Kaarkainen et al. do not provide any teaching or suggestion for measuring a level of fluid in a test tube that is held by a holder wherein the control unit determines an erythrocyte sedimentation rate as claimed. The detection of the level of fluid in the test tubes is a critical in the present invention because the erythrocyte sedimentation rate is determined based on the detected levels of the fluid. Skotnikov et al. and Kaarkainen et al. fail to disclose such erythrocyte sedimentation rate determining features. In fact, Skotnikov et al. and Kaarkainen et al. do not teach or suggest any measuring arrangement based on detection of levels measured at two positions spaced apart from one another by a sedimentation area as claimed. Accordingly, the rejection should be reversed with respect to claims 18, 19 and 20 as the prior art as a whole does not establish a prima facie case of obviousness as the prior art as a whole does not teach or suggest each and every feature as recited in the claimed combination.

CONCLUSION

The cited prior art references fail to teach or suggest the crux of the invention. The invention presents a novel combination of features. The prior art fails to suggest similar ideas and fails to suggest the structural combination as claimed. Accordingly, it is requested that the Examiner's rejections be reversed.

ISSUE: Whether claims 29, 30 and 32-34 are rejectable under 35 U.S.C. 103(a) as being

unpatentable over Skotnikov et al. in view of Coulter et al. (US 4,609,017).

CLAIM 29

Skotnikov et al. and Coulter et al. do not provide any teaching or suggestion for two detectors that measure levels of biological fluid in test tubes held by holders wherein a setup unit comprises at least one first conveyor for moving a plurality of racks containing test tubes with samples of biological fluid as claimed. The detection of the level of fluid in the test tubes is a significant feature of the present invention because the erythrocyte sedimentation rate is determined based on the detected levels of the fluid. Skotnikov et al. and Coulter et al. fail to disclose such erythrocyte sedimentation rate determining features. Accordingly, the rejection should be reversed with respect to claim 29 as the prior art as a whole does not establish a prima facie case of obviousness as the prior art as a whole does not teach or suggest each and every feature as recited in the claimed combination.

CLAIM 30

The final rejection relies on Coulter et al. to teach a first transfer unit that removes single racks from a first conveyor and transfers the single racks to a reading station as featured in the present invention. Specifically the final rejection takes the position that the input compartment 16 is the equivalent of the first transfer unit of the present invention. Appellant respectfully disagrees with this interpretation of Coulter et al. The input compartment 16 of Coulter et al. does not remove the carrier 28 and does not transfer the single racks to a reading

station as claimed. The input compartment 16 merely has fingers 56 and 58 that release a carrier 28 on to an elevator 20 that delivers the carrier 28 to a conveyor belt 32 as clearly shown in Figure 2. However, the input compartment 16 does not remove single racks from the elevator 20 and transfer the single racks to the reading station as claimed. As such, the prior art as a whole takes a completely different approach. Accordingly, the rejection should be reversed with respect to claim 30 as the prior art as a whole does not establish a prima facie case of obviousness as the prior art as a whole does not teach or suggest each and every feature as recited in the claimed combination.

CLAIM 32

The prior art references as a whole fail to teach and fail to suggest the combination of a second transfer unit that transfers racks from a second conveyor to a first conveyor as claimed in claim 32. The final rejection relies on Coulter et al. to teach a setup unit that includes a second conveyor for moving a plurality of racks and a second transfer device for transferring the racks from the second conveyor to a first conveyor. Specifically the final rejection takes the position that the aspiration station 40 is the equivalent of the second transfer device of the present invention. Appellant respectfully disagrees with this interpretation of Coulter et al. Coulter et al. only discloses an input compartment 16 that has fingers 58, 60 that release a carrier 28 on to an elevator 20 wherein the elevator 20 delivers the carrier 28 to a conveyor belt 32. There is no teaching or suggestion in Coulter et al. that the aspiration station 40 transfers racks of test tubes from the conveyor belt 32 to the elevator 20 as claimed in claim 32.

Accordingly, the rejection should be reversed with respect to claim 30 as the prior art as a whole does not establish a prima facie case of obviousness as the prior art as a whole does not teach or suggest each and every feature as recited in the claimed combination.

CLAIM 33

The cited prior art references as a whole do not teach or suggest the combination of a first transfer device that transfers racks of test tubes from a first conveyor to a reading station and from the reading station to a second conveyor as featured in claim 33. The final rejection takes the position that the input compartment 16 of Coulter et al. is the equivalent of the first transfer unit of the present invention. However, the input compartment 16 of Coulter et al. only releases a carrier 28 to an elevator 20 wherein the elevator 20 delivers the carrier 28 to a conveyor belt 32. The input compartment 16 of Coulter et al. does not transfer racks of test tubes to two different conveyors as claimed. As such, the prior art as a whole does not direct a person of ordinary skill in the art toward critical features of the claimed combination. Accordingly, the rejection should be reversed with respect to claim 33 as the prior art as a whole does not establish a prima facie case of obviousness as the prior art as a whole does not teach or suggest each and every feature as recited in the claimed combination.

CLAIM 34

Skotnikov et al. and Coulter et al. fail to teach and fail to suggest the combination of a means for identifying the status of each rack associated with one or more of a first conveyor

and a second conveyor of a setup unit as claimed. The final rejection relies on Column 8, lines 50-68 of Coulter et al. to teach that it would be obvious to provide a means for identifying the status of each rack associated with one or more conveyors of a setup unit as featured in the present invention. Column 8, lines 50-68 of Coulter et al. merely teaches that reading of a sample identification label can be done in one movement or in a forward and return movements. However, there is no teaching and no suggestion in Column 8, lines 50-68 of Coulter et al. for identifying the status of each rack associated with one or more of a first conveyor and a second conveyor as claimed. The means for identifying the status of each rack in the present invention advantageously determines whether the test tubes need to be subjected to the erythrocyte sedimentation rate determination process. Compared with the present invention, Column 8, lines 50-68 does not teach or suggest that the status of each rack associated with one or more conveyors is identified as recited in claim 34. Accordingly, the rejection should be reversed with respect to claim 34 as the prior art as a whole does not establish a prima facie case of obviousness as the prior art as a whole does not teach or suggest each and every feature as recited in the claimed combination.

CONCLUSION

The cited prior art references fail to teach or suggest the crux of the invention. The invention presents a novel combination of features. The prior art fails to suggest similar ideas and fails to suggest the structural combination as claimed. Accordingly, it is requested that the Examiner's rejections be reversed.

ISSUE: Whether claim 31 is rejectable under 35 U.S.C. 103(a) as being unpatentable over Skotnikov et al. in view of Coulter et al. and in further view of Roginski (US 4,927,545).

Skotnikov et al., Coulter et al. and Roginski fail to teach or suggest the combination of a manipulator comprising a lower push bar and a mobile clamp wherein the lower push bar pushes the test tubes partially out of racks and the mobile clamp removes the test tubes from the racks and insert the test tubes in corresponding holders in a continuous flexible member as claimed. Although Coulter et al. discloses a push rod 32 that pushes a bottom end of a sample tube through and opening in a rack 28 and Roginski discloses a manipulator with a gripper 14, the Coulter et al. and Roginski do not provide any teaching or suggestion for combining the push rod 32 and the gripper 14 in a single manipulator as claimed. Coulter et al. and Roginski do not appreciate the particular problem of having to push a test tube partially out of a rack so that the test tube can be clamped and transferred to a continuous member. Further, the references as a whole fail to teach or suggest that a manipulator that transfers test tubes from racks to a continuous flexible member as claimed. Roginski merely discloses a robotic arm that moves a tube from station to station under the control of a computer, but Roginski does not teach or suggest that the robotic arm transfer the tube to a continuous flexible member as claimed. Accordingly, the rejection should be reversed with respect to claim 31 as the prior art as a whole does not establish a prima facie case of obviousness as the prior art as a whole does not teach or suggest each and every feature as recited in the claimed combination.

CONCLUSION

The cited prior art references fail to teach or suggest the crux of the invention. The invention presents a novel combination of features. The prior art fails to suggest similar ideas and fails to suggest the structural combination as claimed. Accordingly, it is requested that the Examiner's rejections be reversed.

Respectfully submitted
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SHOULD ANY OTHER FEE BE REQUIRED, THE PATENT AND TRADEMARK OFFICE IS HEREBY REQUESTED TO CHARGE SUCH FEE TO OUR DEPOSIT ACCOUNT 13-0410.

(8) CLAIMS APPENDIX

1. An erytrocyte sedimentation rate measuring device for blood samples, the device comprising:

holders for test tubes containing samples of biological fluids;

agitator devices for agitating said test tubes;

at least a first detector and a second detector for detecting the levels inside said test tubes;

a control unit, wherein said holders are formed in a continuous flexible member defining a closed path, said agitator devices, said first detector and said second detector being arranged in sequence along said path, said first detector being located at a spaced location from said second detector via a sedimentation area, said control unit determining the erythrocyte sedimentation rate based on levels inside said test tubes detected by said first detector and said second detector.

2. A device as in claim 1, wherein said agitator devices are arranged and said agitator devices oscillate said holders such that fluid in said holders is stirred.

3. A device as in claim 1, wherein the following are arranged along said closed path:

at least one agitating area, wherein said agitator devices are provided, said sedimentation area being located along said closed path; and

at least one reading area wherein one of said first detector and said second detector is

installed.

4. A device as in claim 1, wherein said flexible member defines a path lying on a substantially horizontal plane.

5. A device as in claim 1, wherein said holders comprise elements interconnected to form a flexible chain member.

6. A device as in claim 5, wherein each of said elements comprises a single seat for a respective test tube.

7. A device as in claim 5, wherein the elements forming said flexible member are connected together by means of couplings, said flexible member moving in a traveling direction, each of said holders being mounted for movement such that each of said holders is rotatable with respect to an adjacent holder about a horizontal axis, said horizontal axis being parallel to said traveling direction, wherein one or more of said holders rotate about said horizontal axis via at least one of said agitator devices, whereby fluid in said one or more of said holders is stirred via said at least one of said agitator devices.

8. A device as in claim 7, wherein said couplings are composed of spherical joints.

9. A device as in claim 4, wherein said agitator devices oscillate said elements forming the flexible chain member such that at least one of said holders rotates about a horizontal axis defined by said continuous flexible member.

10. A device as in claim 9, wherein said agitator devices comprise guides, said elements engaging said guides such that said at least one of said holders rotates about said horizontal axis via said guides.

11. A device as in claim 10, wherein said elements have sliding shoes engaging in said guides.

13. A device as in claim 9, wherein said agitator devices comprise mobile guides, said mobile guides extending along a portion of the path covered by said flexible member, wherein said elements forming the flexible member are engaged, said guides being mounted for movement such that said guides rotate said at least one holder about said horizontal axis, wherein fluid in said at least one holder is mixed via rotation of said at least one holder.

14. A device as in claim 9, wherein said agitator devices comprise a rotor coaxial to a portion of the path of said flexible member and provided with engaging elements for engaging the holders that come to be along said portion along the path of the flexible member, said rotor being mounted for movement such that said rotor rotates or oscillates about an axis

thereof.

15. A device as in claim 14, wherein said engaging elements are in the form of guides within which said holders forming the continuous flexible member are slidingly engaged.

16. A device as in claim 1, wherein said first detector is arranged along said closed path, downstream from the agitator devices, and said second detector is arranged further along said path, downstream from a portion of path defining said sedimentation area.

17. A device as in claim 16, further comprising:

a third detector arranged along said path, downstream from a further portion of path defining a second sedimentation area.

18. A device as in claim 5, wherein said continuous flexible member comprises a transponder associated with each test-tube holder.

19. A device as in claim 5, wherein each of said elements is associated with a respective transponder.

20. A device as in claim 18, wherein along said path there are one or more stations for scanning said transponders.

21. A device as in claim 1, wherein along said closed path there is at least one extractor, for removing the test tubes from said holders.

22. A device as in claim 21, wherein along said closed path there are two extractors for removing the test tubes from said holders and distributing them in respective containers.

23. A device as in claim 1, further comprising automatic manipulators are provided for automatically inserting the test tubes in said holders.

24. A device as in claim 23, wherein said manipulators are move single test tubes from a rack of test tubes and insert said test tubes in said holders.

25. A device as in claim 1, further comprising a setup unit for preparing the test tubes for insertion in said holders.

26. A device as in claim 25, wherein said setup unit is situated above said continuous flexible member.

27. A device as in claim 25, wherein said setup unit comprises a reading station for automatically reading labels attached to said test tubes, to ascertain in each case whether said test tubes must undergo a measurement of the sedimentation rate of the sample contained

therein.

28. A device as in claims 24, wherein said manipulators are controlled and operated by a central unit as a function of information provided for each test tube by reading stations, to transfer the test tubes in which the sedimentation rate must be measured from the rack to a corresponding holder.

29. A device as in claim 25, wherein said setup unit comprises at least one first conveyor for moving a plurality of racks containing test tubes with samples of biological fluid to analyze.

30. A device as in claim 29, wherein said setup unit comprises a first transfer unit for removing single racks from said first conveyor and transferring said single racks to said reading station.

31. A device as in claim 24, wherein said manipulators include a lower push bar, said lower push bar engaging the test tubes contained in the racks such that said test tubes slide partially out of said racks, and said manipulators comprise a mobile clamp for removing the test tubes from the respective racks and inserting said test tubes in corresponding holders in the continuous flexible member.

32. A device as in claim 29, wherein said setup unit includes a second conveyor for moving a plurality of racks and a second transfer device for transferring the racks from the second conveyor to the first conveyor.

33. A device as in claim 32, wherein the first transfer device transfers the racks from the first conveyor to the reading station and from said reading station to the second conveyor.

34. A device as in claim 29, further comprising means for identifying the status of each rack associated with one or more of said first and second conveyors of said setup unit.

41. A device as in accordance with claim 2, wherein along said closed path are arranged said sedimentation area, at least one agitating area, wherein said agitator devices are provided, and at least one reading area wherein one of said first detector and said second detector is installed.

42. A device in accordance with claim 2, wherein said flexible member defines a path lying on a substantially horizontal plane.

43. A device in accordance with claim 3, wherein said flexible member defines a path lying on a substantially horizontal plane.

44. A device in accordance with claim 1, wherein said  holders comprise elements interconnected to form a flexible chain member.

45. A device in accordance with claim 41, wherein along said path, two readings are taken on biological samples in each test tube, the first reading when the test tube leaves the agitation area and second reading at end of the sedimentation area.

46. A device as claimed in claim 1, wherein:

said continuous flexible member comprises elements connected to one another via couplings, wherein consecutive elements are movable with respect to one another about an axis substantially parallel to a travel direction of said continuous felxible member via said couplings such that each of said elements is rotatable about said axis via at least one of said agitator devices; and

each element comprises at least one seat for one of the test tubes, said at least one of said agitator devices rotating one or more of said elements about said axis such that blood samples contained in said test tubes are mixed via rotation of said elements.

47. A device according to claim 46, wherein said agitation device comprises a rotor and guides, said rotor being mounted for movement such that said rotor rotates about said axis, wherein consecutive elements move along said guides and across said rotor when said elements are advanced along said path, whereby said consecutive elements engage said guides, said rotor

rotating said elements and the test tubes held by said seats about said axis.

48. An erythrocyte sedimentation rate measuring device for blood samples, the device comprising:

a plurality of test tubes, each of said test tubes comprising samples of biological fluids;

a plurality of holders, one of said test tubes being inserted into at least one of said holders, each of said holders being connected to an adjacent holder to define an endless flexible member, said endless flexible member being movable along a closed path, each of said holders being rotatable about a horizontal axis with respect to said adjacent holder;

a plurality of agitator devices, at least one of said agitator devices receiving one or more of said holders such that said one or more of said holders is rotated about said horizontal axis, wherein said biological fluids in said one or more of said holders is mixed via rotation of said holders;

a first detector;

a second detector;

a control unit, said agitator devices, said first detector and said second detector being arranged along said closed path, said first detector being arranged adjacent to at least one of said agitator devices, said second detector being disposed downstream of said first detector and said agitator devices, wherein a portion of said endless flexible member extending between said first detector and said second detector defines a sedimentation area, said first detector detecting a first level of said biological fluids in said one or more holders after said one or

more holders are rotated by said agitator devices, said second detector detecting a second level of said biological fluids in said one or more holders after said one or more holders are moved along said sedimentation area, said control unit determining an erythrocyte sedimentation rate based on said first level and said second level of said biological fluids.

49. A device according to claim 48, wherein said at least one of said agitator devices rotates said one or more holders from between a first position and a second position, said one or more holders being in a substantially vertical position in said first position, said one or more holders being in a non-vertical position in said second position.

50. A device as in claim 48, wherein said holders via coupling elements, said flexible member moving in a traveling direction, wherein one or more of said holders rotate about said horizontal axis via said coupling elements.

51. An erythrocyte sedimentation rate measuring device for blood samples, the device comprising:

a plurality of test tubes, each of said test tubes comprising samples of biological fluids;

a plurality of holders, one of said test tubes being inserted into at least one of said holders, each of said holders being connected to an adjacent holder to define an endless flexible member, said endless flexible member being movable along a closed path, each of said holders being rotatable about a horizontal axis with respect to said adjacent holder;

a holder rotating means for receiving one or more of said holders and rotating said one or more of said holders about said horizontal axis such that the biological fluids in said test tubes are mixed via rotation of said holders;

a first detector;

a second detector;

a control unit, said holder rotating means, said first detector and said second detector being arranged along said closed path, said first detector being arranged adjacent to said holder rotating means, said second detector being disposed downstream of said first detector, wherein a portion of said endless flexible member extends between said first detector and said second detector, said portion of said endless flexible member defining a sedimentation area, said first detector detecting a first level of said biological fluids in said one or more holders after said one or more holders are rotated by said holder rotating means, said one or more holders being moved along said sedimentation area after being detected by said first detector, said second detector detecting a second level of said biological fluids in said one or more holders after said one or more holders are moved along said sedimentation area, said control unit determining an erythrocyte sedimentation rate based on said first level and said second level of said biological fluids.

52. A device according to claim 51, wherein said holder rotating means rotates said one or more holders from between a first position and a second position, said one or more holders being in a substantially vertical position in said first position, said one or more holders

being in a non-vertical position in said second position.

(9) Evidence appendix

NONE

(10) Related proceedings appendix

NONE